LOUISIANA BLUE

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Extracranial Carotid Angioplasty Stenting is addressed separately in medical policy 00155.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider percutaneous intracranial artery stent placement with or without angioplasty as part of the treatment of individuals with an intracranial aneurysm when ALL of the following criteria are met to be **eligible for coverage:****

- Surgical treatment is not appropriate or attempted surgery was unsuccessful; **and**
- Standard endovascular techniques (coiling) are inadequate to achieve complete isolation of the aneurysm because of anatomic considerations which include, but are not limited to:
  - wide-neck aneurysm (4 mm or more); **or**
  - sack-to-neck ratio less than 2:1.

Based on review of available data, the Company may consider the use of endovascular mechanical embolectomy using a device with U.S. Food and Drug Administration (FDA) approval for the treatment of acute ischemic stroke to be **eligible for coverage**** as part of the treatment of acute ischemic stroke for individuals that meet the patient selection criteria.

Patient Selection Criteria

Coverage eligibility for the use of endovascular mechanical embolectomy using a device with FDA approval for the treatment of acute ischemic stroke will be considered when ALL of the criteria below is met:

- Have a demonstrated occlusion within the proximal intracranial anterior circulation (intracranial internal carotid artery, or M1 or M2 segments of the middle cerebral artery, or A1 or A2 segments of the anterior cerebral artery); AND
- Can receive endovascular mechanical embolectomy within 12 hours of symptom onset OR within 24 hours of symptom onset if there is evidence of a mismatch between specific clinical and imaging criteria (see Policy Guidelines); AND

- Have evidence of substantial and clinically significant neurologic deficits (see Policy Guidelines section); AND
- Have evidence of salvageable brain tissue in the affected vascular territory (see Policy Guidelines section); AND
- Have no evidence of intracranial hemorrhage or arterial dissection on computed tomography (CT) or magnetic resonance imaging (MRI).

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers intracranial stent placement in the treatment of intracranial aneurysms, except as noted above, to be **investigational.***

Based on review of available data, the Company considers intracranial percutaneous transluminal angioplasty with or without stenting in the treatment of atherosclerotic cerebrovascular disease to be **investigational.***

Based on review of available data, the Company considers endovascular interventions for the treatment of acute ischemic stroke when the above criteria are not met to be **investigational.***

Policy Guidelines

Selection of Individuals for Endovascular Mechanical Embolectomy for Acute Ischemic Stroke

The major randomized controlled trials (RCTs) demonstrating a benefit with endovascular mechanical embolectomy vary in criteria for selecting individuals based on the presence or absence of salvageable brain tissue. Several RCTs use the Alberta Stroke Program Early Computed Tomography Score, which is a 10-point quantitative computed tomography (CT) score to assess the presence of early ischemic changes. MR CLEAN (Endovascular treatment for acute ischemic stroke in the Netherlands) (Berkhemer et al 2015) did not specify imaging criteria to demonstrate salvageable brain tissue. Table PG1 lists the criteria used by other trials.

Table PG1. Trial Selection Criteria for Salvageable Brain Tissue

Trial	Inclusion or Exclusion	Criteria
REVASCAT (Jovin et al 2015)	Exclusion	Hypodensity on CT or restricted diffusion demonstrated by:

		• An ASPECTS <7 on CT, CT perfusion CBV, CTA source imaging; OR • An ASPECTS <6 on DWI MRI
ESCAPE (Goyal et al 2015)	Exclusion	Baseline non-contrast CT with extensive early ischemic changes of ASPECTS of 0-5 in the territory of symptomatic intracranial occlusion; OR other confirmation of a moderate-to-large core defined 1 of 3 ways: • On a single-phase, multiphase, or dynamic CTA: no or minimal collaterals in a region greater than 50% of the MCA territory when compared with pial filling on the contralateral side (multiphase/dynamic CTA preferred); OR • On CT perfusion (>8 cm coverage): a low CBV and very low CBF, ASPECTS <6 AND in the symptomatic MCA territory; OR • On CT perfusion (<8 cm coverage): a region of low CBV and very low CBF greater than one-third of the CT perfusion-imaged symptomatic MCA territory
EXTEND-IA (Campbell et al 2015)	Inclusion	Based on CT perfusion imaging using CT or MRI with a Tmax more than 6-s delay perfusion volume and either CT regional CBF or DWI infarct core volume as follows: Mismatch ratio >1.2; AND Absolute mismatch volume >10 mL; AND Infarct core lesion volume <70 mL
SWIFT-PRIME (Saver et al 2015)	Exclusion	Related to imaging-demonstrated core infarct and hypoperfusion: MRI-assessed core infarct lesion greater than: 50 cm^3 for subjects age 18-79 y; 20 cm^3 for subjects age 80-85 y CT-assessed core infarct lesion greater than: 40 cm^3 for subjects age 18-79 y; 15 cm^3 for subjects age 80-85 y For all subjects, severe hypoperfusion lesion (^{3}10-s Tmax lesion >100 cm^3) For all subjects, ischemic penumbra of ≥15 cm^3 and mismatch ratio >1.8

ASPECTS: Alberta Stroke Program Early Computed Tomography Score; CBF: cerebral blood flow; CBV: cerebral blood volume; CT: computed tomography; CTA: computed tomography angiography; DWI: diffusion-weighted imaging; ESCAPE: Endovascular Treatment for Small Core

and Proximal Occlusion Ischemic Stroke; EXTEND-IA: Extending the Time for Thrombolysis in Emergency Neurological Deficits - Intra-Arterial; MCA: middle cerebral artery; MRI: magnetic resonance imaging; REVASCAT: Endovascular Revascularization With Solitaire Device Versus Best Medical Therapy in Anterior Circulation Stroke Within 8 Hours; SWIFT-PRIME: Solitaire With the Intention For Thrombectomy as PRIMary Endovascular Treatment; Tmax: time to maximum.

The RCTs demonstrating a benefit to endovascular mechanical embolectomy in acute stroke generally had some inclusion criteria to reflect stroke severity with the exception of the EXTEND-IA (Extending the Time for Thrombolysis in Emergency Neurological Deficits - Intra-Arterial) trial. The REVASCAT (Endovascular Revascularization With Solitaire Device Versus Best Medical Therapy in Anterior Circulation Stroke Within 8 Hours) and ESCAPE (Endovascular Treatment for Small Core and Proximal Occlusion Ischemic Stroke) trials both required a baseline (poststroke) National Institutes of Health Stroke Scale score of 6 or higher. MR CLEAN specified a clinical diagnosis of acute stroke with a deficit on the National Institutes of Health Stroke Scale score of 2 points or more; SWIFT-PRIME (Solitaire With the Intention For Thrombectomy as PRIMary Endovascular Treatment) specified a National Institutes of Health Stroke Scale score of 8 or more and less than 30 at the time of randomization.

The DAWN (Clinical Mismatch in the Triage of Wake Up and Late Presenting Strokes Undergoing Neurointervention With Trevo) and DEFUSE 3 (Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke 3) studies enrolled individuals from 6 up to 24 hours of the time last time known to be well if there was evidence of a mismatch between specific clinical and imaging criteria (infarct size and volume was assessed with the use of diffusion-weighted magnetic resonance imaging or perfusion CT) (see Table PG2).

Table PG2. Trial Selection Criteria for Individuals 6 to 25 Hours Post Infarct

Trial	Inclusion or Exclusion	Criteria
DAWN Trial (Nogueira et al 2018)	Inclusion	6 to 24 hours related to mismatch between severity of clinical deficit and infarct volume:· ≥80 years of age, score ≥10 on the NIHSS, and had an infarct volume <21 mL; OR· ≤80 years age, score of ≥10 on the NIHSS, and had an infarct volume <31 mL; OR· ≤80 years of age, had a score ≥20 on the NIHSS, and had an infarct volume of 31 to <51 mL
DEFUSE 3 Trial	Inclusion	6 to 16 hours related to mismatch between severity of clinical deficit and infarct volume: Infarct size of <70 mL; AND ratio of ischemic

(Albers et al 2018)		tissue volume to infarct volume of ≥1.8; AND ischemic penumbra of ≥15 cm^3

DAWN: Clinical Mismatch in the Triage of Wake Up and Late Presenting Strokes Undergoing Neurointervention With Trevo; DEFUSE 3: Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke 3; NIHSS: National Institutes of Health Stroke Scale.

Other Policy Guidelines
Flow-diverting stents are indicated for the treatment of large or giant wide-necked intracranial aneurysms, with a size of 10 mm or more and a neck diameter of 4 mm or more, in the internal carotid artery from the petrous to the superior hypophyseal segments.

This policy only addresses endovascular therapies used on intracranial vessels.

These policy statements are not intended to address the use of rescue endovascular therapies, including intra-arterial vasodilator infusion and intracranial percutaneous transluminal angiography, in delayed cerebral ischemia after aneurysmal subarachnoid hemorrhage.

Background/Overview

Cerebrovascular Diseases
Cerebrovascular diseases include a range of processes affecting the cerebral vascular system, including arterial thromboembolism, arterial stenosis, and arterial aneurysms, all of which can restrict cerebral blood flow due to ischemia or hemorrhage. Endovascular techniques, including endovascular mechanical embolectomy with various types of devices (i.e., stents), and angioplasty with or without stenting have been investigated for the treatment of cerebrovascular diseases.

Acute Stroke
Acute stroke is a leading cause of death in the United States; further, it is a leading cause of adult disability. The risk of stroke among Black patients is nearly double the risk among White patients, and Black patients have a higher risk of death due to stroke than other racial groups. Eighty-seven percent of strokes are ischemic and 13% are hemorrhagic. Differentiation between the 2 types of stroke is necessary to determine the appropriate treatment. Ischemic stroke occurs when an artery to the brain is blocked by a blood clot, which forms in the artery (thrombotic), or when another substance (ie, plaque, fatty material) travels to an artery in the brain causing a blockage (embolism). Recanalization of the artery, particularly in the first few hours after occlusion, reduces rates of disability and death.

Racial differences in the utilization of endovascular therapy for acute stroke have been reported. Sheriff et al (2022) analyzed the Get With The Guidelines-Stroke database; between 2015 and 2019, Black patients had lower odds of receiving endovascular therapy compared to non-Hispanic Whites

(adjusted odds ratio [aOR], 0.83; 95% confidence interval [CI], 0.76 to 0.90). At 3 months, functional independence as assessed by the modified Rankin Scale was less common among Black (aOR, 0.84; 95% CI, 0.75 to 0.95) and Asian (aOR, 0.79; 95% CI, 0.65 to 0.98) individuals compared to non-Hispanic Whites. de Havenon et al (2021) found that Black patients were less likely to receive endovascular therapy compared to White patients (odds ratio [OR], 0.75; 95% CI, 0.70 to 0.81) according to National Inpatient Sample data from 2016 to 2018. Kim et al (2022) conducted a retrospective study of 40,814 acute ischemic strokes that occurred in Texas during 2019 which found that Black patients received endovascular therapy less frequently than White patients (4.1% vs. 5.3%, respectively; adjusted relative risk [aRR], 0.76; 95% CI, 0.66 to 0.88; p<.001) despite similar rates of hospital admission. The rate of receipt of endovascular therapy was similar between White and Hispanic patients.

Intracranial Arterial Stenosis
It is estimated that intracranial atherosclerosis causes about 8% of all ischemic strokes. Intracranial stenosis may contribute to stroke in 2 ways: either due to embolism or low-flow ischemia in the absence of collateral circulation. Recurrent annual stroke rates are estimated at 4% to 12% per year with atherosclerosis of the intracranial anterior circulation and 2.5% to 15% per year with lesions of the posterior (vertebrobasilar) circulation.

Intracranial Aneurysms
Compared with acute ischemic stroke, cerebral aneurysms have a much lower incidence in the United States, with prevalence between 0.5% and 6% of the population. However, they are associated with significant morbidity and mortality due to subarachnoid hemorrhage resulting from aneurysm rupture.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Several devices for endovascular treatment of intracranial arterial disease were cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process or the humanitarian device exemption process. By indication, approved devices are as follows.

Acute Stroke
Table 1 summarizes the first generation devices with FDA clearance for the endovascular treatment of acute stroke and subsequent approval of stent retrievers.

Table 1. Food and Drug Administration-Cleared Mechanical Embolectomy Devices for Acute Stroke

Device	510(k) No. for Original Device	Approval Date for Original Device	Indications
Penumbra System®‡ (Reperfusion Catheter RED™ 43)	K222808	Dec 2022	Patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease within 8 h of symptom onset who are ineligible for or who fail IV tPA
Esperance™‡ Aspiration Catheter System (Wallaby Medical)	K211697	Nov 2021	Patients with acute ischemic stroke within 8 h of symptom onset who are ineligible for or who fail IV tPA
Embotrap®‡ III Revascularization Device (Neuravi Ltd)	K211338	July 2021	Patients with acute ischemic stroke within 8 h of symptom onset who are ineligible for or who fail IV tPA
ZOOM™‡ 71 Reperfusion Catheter (Imperative Care, Inc)	K211476	June 2021	Patients with acute ischemic stroke within 8 h of symptom onset who are ineligible for or who fail IV tPA
ZOOM Reperfusion Catheter (Imperative Care, Inc)	K210996	April 2021	Patients with acute ischemic stroke within 8 h of symptom onset who are ineligible for or who fail IV tPA
Tigertriever™‡ and Tigertriever 17 Resvascularization Devices (Rapid Medical, Ltd)	K203592	Mar 2021	Patients with acute ischemic stroke within 8 h of symptom onset who are ineligible for or who fail IV tPA
Merci®‡ Retriever (Concentric Medical; acquired by Stryker Neurovascular in 2011)	K033736	Aug 2004 (modified device approved May 2006)	Patients with acute ischemic stroke and who are ineligible for or who fail IV tPA therapy
Penumbra System®‡ (Penumbra)	K072718	Dec 2007	Patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease within 8 h of symptom onset
Stent retrievers			

Solitaire™‡ FR Revascularization Device (Covidien/ev3 Neurovascular)	K113455	Mar 2012	Patients with acute ischemic stroke due to large intracranial vessel occlusion who are ineligible for or who fail IV tPA
Trevo®‡ NXT ProVue Retriever (Stryker Neurovascular)	K210502	Aug 2021	Patients with acute ischemic stroke within 6 h of symptom onset who fail IV tPA; patients with acute ischemic stroke within 8 h of symptom onset who are ineligible for or who fail IV tPA; patients with smaller core infarcts may start therapy as late as 24 h after last seen well
Trevo®‡ Retriever device (Stryker Neurovascular)	K122478	Aug 2012	Patients with acute ischemic stroke due to large intracranial vessel occlusion who are ineligible for or who fail IV tPA
EmboTrap®‡ II Revascularization Device	K173452	May 2018	Patients with ischemic stroke within 8 hours of symptom onset who are ineligible for or who fail IV tPA

IV: intravenous; tPA: tissue plasminogen activator.

Intracranial Arterial Stenosis
Two devices were approved by the FDA through the humanitarian device exemption process for atherosclerotic disease. This form of FDA approval is available for devices used to treat conditions with an incident rate of 4000 or fewer cases per year; the FDA only requires data showing "probable safety and effectiveness." Devices with their labeled indications are as follows.

Neurolink System®‡
"The Neurolink system [Guidant] is indicated for the treatment of patients with recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy in intracranial vessels ranging from 2.5 to 4.5 mm in diameter with ≥50% stenosis and that are accessible to the stent system."

Wingspan™‡ Stent System
"The Wingspan Stent System [Boston Scientific] with Gateway PTA [percutaneous transluminal angioplasty] Balloon Catheter is indicated for use in improving cerebral artery lumen diameter in

patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with ≥50% stenosis that are accessible to the system."

Intracranial Aneurysms
In 2011, the Pipeline®‡ Embolization Device (Covidien/eV3 Neurovascular), an intracranial aneurysm flow-diverter, was approved by the FDA through the premarket approval process (P100018) for the endovascular treatment of adults (≥22 years) with large or giant wide-necked intracranial aneurysms in the internal carotid artery from the petrous to the superior hypophyseal segments. Approval was based on the Pipeline for Uncoilable for Failed Aneurysms Study, a single-arm, open-label feasibility study, reported by Becske et al (2013) that included 108 patients, aged 30 to 75 years, with unruptured large and giant wide-necked aneurysms.

In 2018, Surpass Streamline™‡ Flow Diverter (Stryker Neurovascular) was approved by the FDA through the premarket approval process (P170024) for use in the endovascular treatment of patients (18 years of age and older) with unruptured large or giant saccular wide-neck (neck width ≥4 mm or dome-to-neck ratio <2) or fusiform intracranial aneurysms in the internal carotid artery from the petrous segment to the terminus arising from a parent vessel with a diameter ≥2.5 mm and ≤5.3 mm. The approval was based on 1 year results of the Surpass Intracranial Aneurysm Embolization System Pivotal Trial to Treat Large or Giant Wide Neck Aneurysms (SCENT) study. The SCENT study is continuing follow-up to 5 years post-procedure as a post-approval study.

The following stents have been approved by the FDA through the humanitarian device exemption process for treatment of intracranial aneurysms.

Neuroform™‡ Microdelivery Stent System
In 2002, based on a series of approximately 30 patients with 6-month follow-up, the Neuroform Microdelivery Stent System (Stryker) was approved by the FDA through the humanitarian device exemption process (H020002) for use with embolic coils for the treatment of wide-neck intracranial aneurysms that cannot be treated by surgical clipping.

Neuroform™‡ Atlas Stent System
In 2019, the Neuroform Atlas Stent System (Stryker) was approved by the FDA through the premarket approval process (P190031) based on the pivotal ATLAS study including 201 patients with up to 12 months of follow-up. The approved indication is "for use with neurovascular embolization coils in the anterior circulation of the neurovasculature for the endovascular treatment of patients greater than or equal to 18 years of age with saccular wide-necked (neck width greater or equal to 4 mm or a dome-to-neck ratio of <2) intracranial aneurysms arising from a parent vessel with a diameter of greater than or equal to 2.0 mm and less than or equal to 4.5 mm." Product Code: QCA.

Enterprise™‡ Vascular Reconstruction Device and Delivery System
In 2007, based on a series of approximately 30 patients with 6-month follow-up, the Enterprise Vascular Reconstruction Device and Delivery (Cordis Neurovascular) was approved by the FDA through the humanitarian device exemption process (H060001) for use with embolic coils for the treatment of wide-neck, intracranial, saccular or fusiform aneurysms.

The Low-Profile Visualized Intraluminal Support Device
In 2014, the Low-Profile Visualized Intraluminal Support Device (LVIS™ and LVIS™ Jr.; MicroVention)‡ was approved by the FDA through the humanitarian device exemption process (H130005) for use with embolic coils for the treatment of unruptured, wide-neck (neck, ≥4 mm or dome-to-neck ratio, <2), intracranial, saccular aneurysms arising from a parent vessel with a diameter of 2.5 mm or greater and 4.5 mm or smaller. In 2018, the LVIS and LVIS Jr. were approved through the premarket approval process (P170013).

PulseRider®‡ Aneurysm Neck Reconstruction Device
In 2017, the PulseRider Aneurysm Neck Reconstruction Device (Pulsar Vascular, Inc.) was approved by the FDA through the humanitarian device exemption process (H160002) for use with neurovascular embolic coils for treatment of unruptured wide-necked intracranial aneurysms with neck width at least 4 mm or dome to neck ratio greater than 2.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Intracranial arterial disease includes thromboembolic events, vascular stenoses, and aneurysms. Endovascular techniques have been investigated for the treatment of intracranial arterial disease. Endovascular therapy is used as an alternative or adjunct to intravenous tissue plasminogen activator and supportive care for acute stenosis and as an adjunct to risk-factor modification for chronic stenosis. For cerebral aneurysms, stent-assisted coiling and the use of flow-diverting stents have been evaluated as an alternative to endovascular coiling in patients whose anatomy is not amenable to simple coiling.

Summary of Evidence
For individuals who have an acute ischemic stroke due to occlusion of an anterior circulation vessel who receive endovascular mechanical embolectomy, the evidence includes randomized controlled trials (RCTs) comparing endovascular therapy with standard care and systematic reviews of these RCTs. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-

related mortality and morbidity. From 2013 to 2015, 8 RCTs were published comparing endovascular therapies with noninterventional care for acute stroke in patients with anterior circulation occlusions. Several trials that were ongoing at the time of publication of these 8 RCTs were stopped early, and results with the limited enrollment have been published. Trials published from 2014 to 2015 demonstrated a significant benefit regarding reduced disability at 90 days posttreatment. The trials that demonstrated a benefit for endovascular therapy either exclusively used stent retriever devices or allowed the treating physician to select a device, mostly a stent retriever device, and had high rates of mechanical embolectomy device use in patients randomized to endovascular therapy. Studies that demonstrated a benefit for endovascular therapy required demonstration of a large vessel, anterior circulation occlusion for enrollment. Also, they were characterized by fast time-to-treatment. Not all studies published after 2015 have shown a benefit of endovascular therapy in major clinical outcomes, possibly due to small sample sizes and lack of power to detect differences, but systematic reviews have found significant effects. Two trials published in 2018 demonstrated that it was possible to extend the window for mechanical thrombectomy up to about 24 hours for select patients. To achieve results in real-world settings similar to those in clinical trials, treatment times, clinical protocols, and patient selection criteria should be similar to those in RCTs. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have an acute ischemic stroke due to basilar artery occlusion who receive endovascular mechanical embolectomy, the evidence includes 4 RCTs and systematic reviews of these RCTs and observational studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. Results among these studies are inconsistent for functional outcomes and 90-day mortality. Systematic reviews of both RCTs and observational studies support the efficacy of endovascular therapy for improving functional outcomes and reducing mortality, but rates of symptomatic intracranial hemorrhage are higher with endovascular intervention than with medical therapy. The generalizability of the RCT results may be limited due to lack of inclusion of any U.S. populations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have symptomatic intracranial arterial stenosis due to atherosclerosis who receive intracranial percutaneous transluminal angioplasty with or without stenting, the evidence includes systematic reviews and 3 major RCTs. Relevant outcomes are overall survival, symptoms, morbid events, functional outcomes, and treatment-related mortality and morbidity. All available RCTs have demonstrated no significant benefit with endovascular therapy. In particular, the Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) trial was stopped early due to harms, because the rate of stroke or death at 30 days posttreatment was higher in the endovascular arm, which received percutaneous angioplasty with stenting. Follow-up of SAMMPRIS subjects has demonstrated no long-term benefit from endovascular therapy. Although some nonrandomized studies have suggested a benefit from endovascular therapy, the available evidence from 3 RCTs does not suggest that intracranial

percutaneous transluminal angioplasty with or without stenting improves outcomes for individuals with symptomatic intracranial stenosis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have intracranial aneurysm(s) who receive endovascular coiling with intracranial stent placement or intracranial placement of a flow-diverting stent, the evidence includes RCTs, several nonrandomized comparative studies, and multiple single-arm studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. The available nonrandomized comparative studies have reported occlusion rates for stent-assisted coiling that are similar to or higher than coiling alone and recurrence rates that may be lower than those for coiling alone. For stent-assisted coiling with self-expanding stents, some evidence has also shown that adverse event rates are relatively high, and a nonrandomized comparative trial has reported that mortality is higher with stent-assisted coiling than with coiling alone. For placement of flow-diverting stents, a pragmatic RCT and registry study have compared flow diversion with standard management (observation, coil embolization, or parent vessel occlusion) in patients for whom flow diversion was considered a promising treatment. The pragmatic study was stopped early after crossing a predefined safety boundary when 16% of patients treated with flow diversion were dead or dependent at 3 months or later. Flow diversion was also not as effective as the investigators had hypothesized. A systematic review comparing the flow-diverting stents with endovascular coiling for intracranial aneurysms has demonstrated higher rates of aneurysm obliteration in those treated with the Pipeline endovascular device than those treated with coiling, with similar rates of good clinical outcomes. The evidence does not provide high certainty whether stent-assisted coiling or placement of a flow-diverting stent improves outcomes for patients with intracranial aneurysms because the risk-benefit ratio cannot be adequately defined. One randomized study demonstrated adequate aneurysm occlusion with the Surpass flow diverter device. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2014 Input

In response to requests, input was received from 4 physician specialty societies and 2 academic medical centers while this policy was under review in 2014. Input focused on the use of flow-diverting stents such as the Pipeline Embolization Device for the treatment of intracranial aneurysms. There was general support for the use of intracranial stent placement for intracranial

aneurysms meeting the criteria outlined in the policy statements. There was also general support for the use of flow-diverting stents for the treatment of intracranial aneurysms and general support for the statement that flow-diverting stents are preferable to other stents for certain aneurysm characteristics.

There was general support for the use of endovascular interventions for the treatment of acute stroke, particularly for: (1) patients who have failed to respond to intravenous (IV) tissue plasminogen activator (tPA); and (2) patients who present outside the range of time for which tPA would be considered (≤8 hours of last known normal state or symptom onset).

2011 Input
In response to requests, input was received from 3 physician specialty societies and 3 academic medical centers while this policy was under review in 2011. For treatment of intracranial stenosis, most providing input would consider the use of this technology in selected patients who remained symptomatic from intracranial atherosclerotic disease, despite maximum medical therapy. There was unanimous support for the use of this technology in select patients with intracranial aneurysms; i.e., in those patients for whom surgical treatment is not possible and for whom endovascular treatment (coils) does not completely isolate the aneurysm.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Society of Vascular and Interventional Neurology
In 2016, the Society of Vascular and Interventional Neurology published recommendations on comprehensive stroke center requirements and endovascular stroke systems of care. The recommendations were based on 5 multicenter, prospective, randomized, open-label, blinded endpoint clinical trials that demonstrated the benefits of endovascular therapy with mechanical thrombectomy in acute ischemic strokes with large vessel occlusions. Their recommendation pertinent to this evidence review is:

"Endovascular mechanical thrombectomy, in addition to treatment with IV tPA in eligible patients, is recommended for anterior circulation large vessel occlusion ischemic strokes in patients presenting within 6 h of symptom onset."

American Heart Association and American Stroke Association
In 2018, the American Heart Association (AHA) and the American Stroke Association (ASA) (update 2019) published joint guidelines on the early management of patients with acute ischemic

stroke (Table 2). These guidelines included several recommendations relevant to the use of endovascular therapies for acute stroke.

Table 2. Recommendations on Use of Endovascular Therapies to Manage Acute Stroke

Recommendation	COR	LOE
"Mechanical thrombectomy requires the patient to be at an experienced stroke center with rapid access to cerebral angiography, qualified neurointerventionalists, and a comprehensive periprocedural care team. Systems should be designed, executed, and monitored to emphasize expeditious assessment and treatment. Outcomes for all patients should be tracked. Facilities are encouraged to define criteria that can be used to credential individuals who can perform safe and timely intra-arterial revascularization procedures."	I	C
"Patients should receive mechanical thrombectomy with a stent retriever if they meet all the following criteria: • "Prestroke mRS score 0 to 1, • Causative occlusion of the internal carotid artery or MCA (M1), • Age ≥18 years, • NIHSS score of ≥6, • ASPECTS of ≥6, and • "Treatment can be initiated (groin puncture) within 6 hours of symptom onset."	I	A
In selected patients with acute ischemic stroke within 6 to 16 hours of last known normal who have LVO in the anterior circulation and meet other DAWN or DEFUSE 3 eligibility criteria, mechanical thrombectomy is recommended.	I	A
"The technical goal of the thrombectomy procedure should be a reperfusion to a modified TICI 2b/3 angiographic result to maximize the probability of a good functional clinical outcome."	I	A
As with intravenous alteplase, reduced time from symptom onset to reperfusion with endovascular therapies is highly associated with better clinical outcomes. To ensure benefit, reperfusion to TICI grade 2b/3 should be achieved as early as possible and within the therapeutic window."	I	B-R

Recommendation	COR	LOE
"Use of stent retrievers is indicated in preference to the MERCI device. The use of mechanical thrombectomy devices other than stent retrievers may be reasonable in some circumstances."	IIIb	AB-NR
“The use of proximal balloon guide catheter or a large bore distal access catheter rather than a cervical guide catheter alone in conjunction with stent retrievers may be beneficial. Future studies should examine which systems provide the highest recanalization rates with the lowest risk for nontarget embolization.”	IIa	C-LD
In selected patients with acute ischemic stroke within 16 to 24 hours of last known normal who have LVO in the anterior circulation and meet other DAWN eligibility criteria, mechanical thrombectomy is reasonable.	IIa	B-R
“In carefully selected patients with anterior circulation occlusion who have contraindications to intravenous r-tPA, endovascular therapy with stent retrievers completed within 6 hours of stroke onset is reasonable. There are inadequate data available at this time to determine the clinical efficacy of endovascular therapy with stent retrievers for those patients whose contraindications are time-based or nontime-based (eg, prior stroke, serious head trauma, hemorrhagic coagulopathy, or receiving anticoagulant medications).”	IIa	C
“Although the benefits are uncertain, use of mechanical thrombectomy with stent retrievers may be reasonable for carefully selected patients with acute ischemic stroke in whom treatment can be initiated (groin puncture) within 6 hours of symptom onset and who have causative occlusion of the M2 or M3 portion of the MCAs.”	IIb	B-R
“Although the benefits are uncertain, use of mechanical thrombectomy with stent retrievers may be reasonable for carefully selected patients with acute ischemic stroke in whom treatment can be initiated (groin puncture) within 6 hours of symptom onset and who have causative occlusion of the anterior cerebral arteries, vertebral arteries, basilar artery, or posterior cerebral arteries.”	IIb	C
“Although the benefits are uncertain, use of mechanical thrombectomy with stent retrievers may be reasonable for patients with acute ischemic stroke in whom treatment can be initiated (groin puncture) within 6 hours of symptom onset and who have prestroke mRS score of >1, ASPECTS <6, or NIHSS score <6 and causative occlusion of the internal carotid artery or proximal MCA (M1). Additional randomized trial data are needed.”	IIb	B-R
In patients under consideration for mechanical thrombectomy, observation after IV alteplase to assess for clinical response should not be performed.	III	B-R

Recommendation	COR	LOE
"Use of salvage technical adjuncts including intra-arterial fibrinolysis may be reasonable to achieve these angiographic results"	IIb	C-LD
"Intra-arterial fibrinolysis initiated within 6 hours of stroke onset in carefully selected patients who have contraindications to the use of intravenous alteplase might be considered, but the consequences are unknown."	IIb	C-EO

ASPECTS: Alberta Stroke Program Early Computed Tomography Score; COR: class of recommendation; DAWN: Clinical Mismatch in the Triage of Wake Up and Late Presenting Strokes Undergoing Neurointervention With Trevo; DEFUSE 3: Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke 3; IV: intravenous;LOE: level of recommendation; LVO: large vessel occlusion; MCA: middle cerebral artery; mRS: modified Rankin Scale; NIHSS: National Institutes of Health Stroke Scale; r-tPA: recombinant tissue plasminogen activator; TICI: Thrombolysis in Cerebral Infarction.

The AHA and ASA also published joint guidelines on the management of patients with unruptured intracranial aneurysms in 2015.These guidelines included the following recommendations relevant to the use of endovascular therapies for aneurysms (Table 2).

Table 2. Recommendations on Management of Unruptured Intracranial Aneurysms

Recommendation	COR	LOE
"...coil embolization may be superior to surgical clipping with respect to procedural morbidity and mortality, length of stay, and hospital costs, so it may be reasonable to choose endovascular therapy over surgical clipping in the treatment of select unruptured intracranial aneurysms, particularly in cases for which surgical morbidity is high, such as at the basilar apex and in the elderly"	IIb	B
"Endovascular treatment of unruptured intracranial aneurysms is recommended to be performed at high-volume centers."	I	B

COR: class of recommendation; LOE: level of recommendation.

In 2022, the AHA and ASA released a scientific statement on endovascular treatment and thrombolysis for acute ischemic stroke in patients with premorbid disability or dementia. The statement reports that several observational studies have evaluated the safety of endovascular therapy (including mechanical thrombectomy) in this patient population which suggests the potential of these patients to retain their pre-stroke level of disability; however, results also show a generally worse prognosis overall and more higher-quality registries and clinical trials are needed to validate results.

U.S. Preventive Services Task Force Recommendations
No U.S. Preventive Services Task Force (USPSTF) recommendations for treatment of intracranial arterial disease were identified. The USPSTF has recommended against screening for asymptomatic carotid artery stenosis in the general population.

Medicare National Coverage
A Medicare national coverage determination on intracranial angioplasty and stenting was released by the Centers for Medicare & Medicaid Services in 2008. This decision was based on a review of available studies at that time, which consisted of several uncontrolled case series. The Centers for Medicare & Medicaid Services review indicated that this evidence was promising and that, while further well-designed randomized controlled trials were needed to confirm whether outcomes were improved, coverage should be allowed. The national coverage determination contained the following coverage determinations:

1. "Medicare coverage for angioplasty and or stenting for symptomatic patients with greater than 70 percent intracranial arterial stenosis; and
2. Medicare coverage for intracranial angioplasty and stenting for other patients within the context of Category B investigational device exemption trials under coverage with evidence development within a registry."

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Endovascular interventions for acute ischemic stroke			
Ongoing			
NCT05983757	A Phase III, Randomized, Multicenter, Investigational, Open Label Clinical Trial That Will Examine Whether Treatment With Endovascular Thrombectomy is Superior to Standard Medical Therapy Alone in Patients Who Suffer a Distal Medium Vessel Occlusion Ischemic Strokes	564	Dec 2026
NCT06143488	Endovascular Therapy Versus Best Medical Treatment for Acute Large Vessel Occlusion Stroke With Low NIHSS	264	Sept 2025

NCT06101667	Efficacy and Safety of Endovascular Recanalization for Acute Basilar Artery Occlusion With Extended Time Window -- A Multicenter, Prospective, Open-label, Blind Endpoint, Randomized Controlled Trial（ANGEL-BAO）	224	Dec 2025
NCT06155032	Study of Rescue Endovascular Therapy for Progressive Acute Mild Ischemic Stroke With Large Vascular Occlusion--- A Multi-centered, Prospective, Open-label, Blind Endpoint, Randomized Controlled Trial (RESCUE END-LOW)	272	Mar 2026
NCT06146790	Evaluation of Endovascular Treatment in Acute Intracranial Distal Medium Vessel Occlusion Stroke - a Multicenter, Randomized Controlled, Clinical Trial	564	Mar 2026
NCT05827042	Endovascular Thrombectomy Alone Versus Intravenous Thrombolysis Plus Endovascular Thrombectomy on Acute Basilar Artery Occlusion - a Multicenter, Randomized Controlled, Clinical Trial	338	Mar 2026
NCT05911568	Treatment With Endovascular Intervention for STroke Patients With Existing Disability	1060	Apr 2028
NCT06289985	STEP: StrokeNet Thrombectomy Endovascular Platform	2000	Sept 2028
NCT03876457	SELECT 2: A Randomized Controlled Trial to Optimize Patient's Selection for Endovascular Treatment in Acute Ischemic Stroke	352	Dec 2023 (active, not recruiting)
NCT02737189	Randomized Trial of Revascularization With Solitaire Stentriever Versus Best Medical Therapy in the Treatment of Acute Ischemic Stroke Due to Basilar Artery Occlusion Presenting Within 6-24 Hours of Symptom Onset	217	Jun 2022 (active, not recruiting)
NCT04551664	Study of Endovascular Therapy in Acute Anterior Circulation Large Vessel Occlusive Patients With a Large Infarct Core (ANGEL-ASPECT)	456	May 2023

NCT04167527	Endovascular Therapy for Low NIHSS Ischemic Strokes	200	Dec 2024
Endovascular interventions for symptomatic intracranial atherosclerotic disease			
Unpublished			
NCT05757505	The Efficacy and Safety of the Intracranial Stent (Tonbridge) in Endovascular Treatment of Symptomatic Intracranial Atherosclerotic Stenosis: A Prospective, Multicenter, Randomized Controlled, Non-inferiority Trial	200	Dec 2025
NCT04631055	A Prospective, Multicenter, Randomized Controlled Clinical Trial to Evaluate the Efficacy and Safety of Intracranial Drug-coated Balloon Catheters in the Treatment of Symptomatic Intracranial Atherosclerotic de Novo Stenosis	180	Apr 2023
Stent-assisted endovascular treatment of intracranial aneurysms			
Ongoing			
NCT05755516	Efficacy and Safety of the Self-expanding Intracranial Stent (Tonbridge) for Endovascular Treatment of Intracranial Aneurysms: A Prospective, Multi-center, Randomized, Open, Parallel Positive Controlled, Non-inferiority Trial	204	Apr 2025
NCT06158087	Prospective, Multicenter, Single-arm Clinical Trial to Evaluate the Safety and Efficacy of pEGASUS Stent System for Assisted Endovascular Treatment of Intracranial Aneurysms	130	Jun 2026
NCT02998229[a]	ARTISSE Aneurysm Treatment Using Intrasaccular Flow Diversion With the ARTISSE™‡ Device	150	Nov 2026
NCT04548856	Microsurgical Clipping and Endovascular Embolization Comparative Prospective Randomized Trial	4	May 2025
Unpublished			

NCT01340612	Stenting in the Treatment of Large, Wide-necked or Recurring Intracranial Aneurysms	205	Apr 2023
NCT03494920	DIRECT-SAFE: A Randomized Controlled Trial of DIRECT Endovascular Clot Retrieval Versus Standard Bridging Thrombolysis With Endovascular Clot Retrieval	295	Sep 2021
NCT03993340	Rescue Stenting for Failed Endovascular Thrombectomy in Acute Ischemic Stroke (ReSET)	78	July 2021

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Policy History

Original Effective Date: 02/23/2006
Current Effective Date: 12/09/2024

02/01/2006	Medical Director review
02/15/2006	Medical Policy Committee review
02/23/2006	Quality Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
04/02/2008	Medical Director review
04/16/2008	Medical Policy Committee approval. No change in policy statement. Rationale totally rewritten with focus on FDA approved devices.
04/02/2009	Medical Director review
04/15/2009	Medical Policy Committee approval. No change to coverage eligibility.
04/08/2010	Medical Policy Committee approval
04/21/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/07/2011	Medical Policy Committee review
04/13/2011	Medical Policy Implementation Committee approval. Changed title from "Percutaneous Transluminal Angioplasty of Intracranial Atherosclerotic Stenoses With or Without Stenting" to "Endovascular Procedures (Angioplasty and/or Stenting) for

	Intracranial Arterial Disease (Atherosclerosis and Aneurysms)". Added that intracranial stent placement is eligible for coverage as part of the endovascular treatment of intracranial aneurysms for patients when surgical treatment is not appropriate and standard endovascular techniques do not allow for complete isolation of the aneurysm, e.g., wide-neck aneurysm (4mm or more) or sack-to-neck ratio less than 2:1. Added that intracranial stent placement in the treatment of intracranial aneurysms, except as noted above, is investigational.
04/12/2012	Medical Policy Committee review
04/25/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/04/2013	Medical Policy Committee review
04/24/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/03/2014	Medical Policy Committee review
04/23/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Policy 00366 (Mechanical Embolectomy for Treatment of Acute Stroke) retired and combined with this policy.
04/02/2015	Medical Policy Committee review
04/20/2015	Medical Policy Implementation Committee approval. Added new coverage statement for Intracranial flow diverting stents with FDA approval and patient selection criterion. Updated rationale and references.
04/07/2016	Medical Policy Committee review
04/20/2016	Medical Policy Implementation Committee approval. Policy statement revised to indicate that mechanical embolectomy for acute stroke may be considered medically necessary with criteria.
10/01/2016	Coding update
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes and CPT coding update.
05/04/2017	Medical Policy Committee review
05/17/2017	Medical Policy Implementation Committee approval. No change to coverage.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. Policy statements changed to reflect extension of the time window for mechanical thrombectomy up to 24 hours after symptom onset for select patients. Added Policy Guidelines section.
01/01/2019	Coding update
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Reformatted the coverage section for clarity.
06/04/2020	Medical Policy Committee review
06/10/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/03/2021	Medical Policy Committee review
06/09/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/02/2022	Medical Policy Committee review
06/08/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

06/01/2023 Medical Policy Committee review
06/14/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/02/2023 Medical Policy Committee review
11/08/2023 Medical Policy Implementation Committee approval. Removed "Based on review of available data, the Company may consider intracranial flow-diverting stents with U.S. Food and Drug Administration (FDA) approval for the treatment of intracranial aneurysms to be eligible for coverage as part of the endovascular treatment of intracranial aneurysms for individuals that meet the patient selection criterion and are not amenable to surgical treatment or standard endovascular therapy.
Patient Selection Criterion
Coverage eligibility for intracranial flow-diverting stents with FDA approval for the treatment of intracranial aneurysms will be considered when the criterion below is met:
Flow-diverting stents are indicated for the treatment of large or giant wide-necked intracranial aneurysms, with a size of 10 mm or more and a neck diameter of 4 mm or more, in the internal carotid artery from the petrous to the superior hypophyseal segments."
Added "Based on review of available data, the Company may consider percutaneous intracranial artery stent placement with or without angioplasty as part of the treatment of individuals with an intracranial aneurysm when ALL of the following criteria are met to be **eligible for coverage:**

- Surgical treatment is not appropriate or attempted surgery was unsuccessful; **and**
- Standard endovascular techniques (coiling) are inadequate to achieve complete isolation of the aneurysm because of anatomic considerations which include, but are not limited to:
  - wide-neck aneurysm (4 mm or more); **or**
  - sack-to-neck ratio less than 2:1."

11/07/2024 Medical Policy Committee review
11/13/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 11/2025

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198
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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	61624, 61630, 61635, 61645 Delete codes effective 12/01/2023: 36227, 36228, 61650, 61651
HCPCS	No codes
ICD-10 Diagnosis	I67.1, Q28.2, Q28.3

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.